PSJ15 Exh 40

Agenda

- Addiction Treatment Business
  - Current Status
  - Direction
- Acquisition Opportunity Overview
  - Company Background
  - Product Information
- Value MI Brings to the Deal
- Strategic Fit
- Financials/Assumptions
- Deal Structure
- Risk Areas
- Next Steps

MI's Addiction Treatment Market

- Demonstrated Reliability as a Supplier
- Utilized Education to Grow the Market
- Leveraged Market Presence (NAMs)
- Established Customer Loyalty
- **Result**: **75% Mkt. Share**

MI's Addiction Treatment Market

Mallinckrodt (AT) Brands

Methadose

- Demonstrated Reliability as a Supplier
- -Utilized Education to Grow the Market
- Leveraged Market Presence (NAMs)
- Established Customer Loyalty
- **Result: 75% Mkt. Share**

Depade

- Utilizing Education to Expand/Create the Market
- MMT and Non-MMT Customers
- Positioned as AT Experts and the Market Leader
- **Result: Good Story to Tell; Last Hope for Success: Progress Being Made**

Britannia Pharmaceuticals

- Based in UK
- Owned by Ajinomoto (Japan) via Forum Holdings
- Specializes in diseases for small populations
- Virtual company
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- Manages business in the UK, licenses elsewhere

Britannia Pharmaceuticals

- Current Product Line
  - Britaject Pen (apomorphine hydrochloride10 mg/mL) for Parkinson's Disease
    - Recently licensed US rights to Mylan
  - Crystapen (benzylpenicillin sodium BP) for meningitis and other bacterial infections
  - OrLAAM (levacetylmethadol) for opiate addiction
    - Removed from the market earlier this year
  - BritLofex (lofexidine hydrochloride) for detoxification from opioids
- Seeking additional dosage forms and/or indications for apomorphine and lofexidine

Lofexidine Hydrochloride

- Rejected as an anti-hypertensive in US due to poor efficacy (Merrell Dow)
- Approved in 1986 in the UK for Opiate Withdrawal (Merrill Dow)
- BPL acquired worldwide rights in 1991(including full toxicology package)
- BPL received a validated UK Product License in 1992 for the Opiate Withdrawal indication and launched it

Lofexidine Hydrochloride

- Is an imidazoline derivative; an á 2-adrenergic agonist
- Form is a package of 60 0.2mg tablets
- MOA - when opioids are stopped abruptly, the brain produces too much noradrenaline (which is thought to cause withdrawal symptoms). Lofexidine reduces the levels of noradrenaline in thereby reducing the symptoms of withdrawal (I.e. chills, sweating, stomach cramps, diarrhea, muscle pain, runny nose and eyes).
- Length of treatment for detoxification is 5-10 days
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Lofexidine Hydrochloride

US Application

- BPL has partnered with NIDA
  - NIDA has acted as FDA liaison since 1996
  - NIDA has provided funding
- Detoxification Indication
  - Phase III trials kicked off 1/17/01
    - Phildelphia (C. O'Brien), LA (W. Ling), and NY (H. Kleber)
  - NIDA has funded these trials
  - Potential for NDA filing in 1-2 years
  - Potential for approval in 2-3 years
  - One box=one detox
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Lofexidine Hydrochloride

US Application

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- Relapse Prevention Indication
  - Claims two brain pathways are involved
    - Drug-induced relapse - naltrexone (2 bottles of 30)
    - Stress-induced relapse - lofexidine (9 boxes of 60)
  - NIDA has funding for these trials
  - Johns Hopkins (A. Umbricht/K. Preston) and Yale (Sinha/Kosten) are the sites
  - 1-2 years behind detoxification application
- Claims of other potential indications - maintenance (methadone adjunct), alcohol, tobacco, cocaine, ADHD, etc...
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Strategic Fit

- Fills void that will exist after Depade takes off
- Improves MI's image (selling detox solutions, not just maintenance) in the field
- Current market leader, need new products to maintain leadership status
- Depade pushes us into detox facilities
- Potential for use in concert with Depade and Methdose
- Open the door for future collaborations
- Rise in abuse of opioids and OBT will increase the number of people in treatment and requiring detox
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Market Approach

- Out-patient and in-patient programs can use (off-label use of clonidine is not good on an out-patient basis)
- MMT Clinics, Hospital Detox Programs currently using methadone (approx. 300), other addiction treatment programs
- 50% return for second detox (repeat business)
- Will be used off-label as an adjunct to methadone, buprenorphine, and naltrexone (alcohol and opiate)
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Deal Structure

- Milestone Payments
  - $350K Completion of Deal (incl. Due diligence)
  - $250K Upon NDA filing (detox)
  - $500k Upon NDA approval (detox)
  - $500K Upon NDA approval (relapse)
  - Margin Split: MI 70%-Britannia 30%
- MI to produce tablets, monitor Phase III trials, and file NDA
- Britannia (via MacFarlan Smith) to supply API to MI exclusively (in North America)
- Contingent on due diligence of regulatory status/progress
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